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# In the Supreme Court of the United States

ALLERGAN, INC. AND ALLERGAN SALES, INC.,
*Petitioners*,

v.

ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON UNIVERSAL, LTD., and BAUSCH & LOMB, INC.,
*Respondents*.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## BRIEF OF GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

Christine J. Siwik
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
(312) 558-5600

William A. Rakoczy
Hugh S. Balsam
Shashank S. Upadhye*
Lara E. Monroe-Sampson
LORD, BISSELL & BROOK LLP
115 South LaSalle Street
Chicago, IL 60603
(312) 443-0700

*Counsel for Amicus Curiae Generic Pharmaceutical Association*

*Counsel of Record

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# BRIEF OF GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

With the consent of the parties, *amicus curiae* Generic Pharmaceutical Association ("GPhA") respectfully submits this brief in opposition to the petition for writ of certiorari.*

## INTEREST OF *AMICUS CURIAE*

GPhA is a national trade association consisting of more than 140 member companies involved in the supply, manufacture, sale, and distribution of generic pharmaceuticals. GPhA advances its members' interests by advocating laws and regulations that encourage the sale of safe, effective, and affordable prescription drugs. This activity benefits the association's members as well as the pharmaceutical industry and the consuming public. In furtherance of its mission, GPhA prepares and disseminates accurate and reliable information about the pharmaceutical industry; participates in legislative, regulatory, and administrative proceedings affecting the industry; and promotes the correct and consistent interpretation by the courts and the U.S. Food and Drug Administration ("FDA") of laws that directly affect the manufacture, distribution, and sale of generic pharmaceutical products.

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* Counsel of record for the parties do not object to the filing of this brief. In accordance with this Court's Rule 37.2(a), those letters have been filed with the Clerk.

In accordance with Rule 37.6, *amicus* states that this brief was authored in its entirety by the counsel listed on the cover, and no person or entity other than the *amicus* listed on the cover made a monetary contribution to the preparation or submission of this brief.

GPhA has an abiding interest in the relationship between patent law and the abbreviated approval process for generic drugs. It seeks to assure that: (1) when patent rights expire, generic drugs can be marketed for all indications that are in the public domain or otherwise off-patent; and (2) the patent laws are not applied in a manner that frustrates Congress's intent to make generic drugs available to consumers upon the expiration of patents that claim the drug or its approved uses. Because the ultimate relief sought by Allergan threatens both these interests, GPhA has a significant stake here and respectfully opposes the petition.

## SUMMARY OF THE ARGUMENT

In the *per curiam* decision below, a unanimous panel of the United States Court of Appeals for the Federal Circuit affirmed summary judgment for the defendants based on the precedential holding in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). There, a unanimous panel held that an action for infringement under 35 U.S.C. § 271(e)(2)(A)—which triggers the automatic 30-month stay of FDA approval of the generic manufacturer's proposed product—is limited to method-of-use patents that claim a use of the NDA drug for which the NDA-holder has actually made the investment to obtain FDA approval. Patents on unapproved, or "off-label," uses (like the patents at issue here and in *Warner-Lambert*) may not be asserted under § 271(e)(2)(A), but may of course be asserted in a traditional infringement action under 35 U.S.C. § 271(b) after ANDA approval and commercial marketing.

Under *Warner-Lambert* and the decision below, NDA-holders may no longer use off-label use patents under § 271(e)(2)(A) as a sword to prevent competition from generic applicants seeking approval to market off-patent drugs for FDA-approved uses. That is precisely what Allergan, and Warner-Lambert before it, accomplished. Merely by asserting patents on unapproved uses for

which they consciously chose not to seek FDA approval, and for which generic applicants could not by law promote, Allergan and Warner-Lambert preserved their lucrative monopolies on off-patent drugs and off-patent FDA-approved uses for years. And both Warner-Lambert and Allergan sought the powerful relief under Hatch-Waxman in § 271(e)(4) that would prevent ANDA applicants from ever marketing their drugs for any use for the life of the off-label use patents, even those FDA-approved off-patent uses in the public domain. Congress, of course, never intended to confer the invaluable 30-month stay and broad § 271(e)(4) relief provided by Hatch-Waxman on NDA-holders like those here that decided not to make the investment required to obtain a new FDA-approved use that might benefit patients.

Allergan's petition tries to revive this cheap but effective means of staving off generic competition by asking this Court to overrule the statutory holding of *Warner-Lambert*. This Court should deny the petition. There is no split of authority or conflict either outside or within the Federal Circuit. The judges of the Federal Circuit have, by their votes, unanimously agreed that *Warner-Lambert* correctly interpreted § 271(e)(2)(A). Rightly so—that interpretation is consistent with the provision's plain language and comports with Hatch-Waxman's patent-listing and certification provisions, as well as Congress's underlying goal of making available to the public more lower-cost generic drugs.

The *per curiam* decision below, like *Warner-Lambert* before it, does not affect, much less restrict, the incentive to invest in research on new uses where, as here, the NDA-holder never made any investment to obtain FDA approval for the new use. Such off-label use patents can still be asserted against generic applicants, albeit without the automatic 30-month stay and the broad § 271(e)(4) relief that is reserved for actions on patents that claim approved uses of the drug.

## ARGUMENT

### I. There is no conflict warranting review.

Because the Federal Circuit has exclusive jurisdiction over all patent appeals, 28 U.S.C. § 1295, there is—and can be—no conflict or split of authority among the various circuit courts of appeals on the proper interpretation of § 271(e)(2)(A). Nor is there any conflict within the Federal Circuit itself, as there was in prior patent decisions of the Federal Circuit reviewed by this Court. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S. Ct. 1831 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 117 S. Ct. 1040 (1997).

The Federal Circuit distributes draft precedential opinions to all active judges for comment before issuance. *See* FED. CIR. INTERNAL OPERATING PROC., RULE 10. Accordingly, the judges of the Federal Circuit, including the judges on the *Allergan* panel below, had the opportunity to comment on the *Warner-Lambert* decision before it issued. *Warner-Lambert* nonetheless issued as a unanimous panel decision.

The *Allergan* draft opinion likewise circulated to all active Federal Circuit judges for comment before it issued. The court could have *sua sponte* ordered *en banc* review, as it has done in the past. *See e.g., Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985) (convening *en banc* to resolve issues under 35 U.S.C. § 102(g)); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (convening *en banc* on limited issue of inequitable-conduct standards); *Johnson & Johnston v. RE Serv.*, Fed. Cir. Docket Nos. 99-1076, -1179, -1180 (Order of Jan. 24, 2001) (*sua sponte* convening *en banc* after panel circulated opinion but before opinion issued); *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, Fed. Cir. Docket Nos. 01-1357, -1376, 02-1221, -1256 (Order of Sept. 26, 2003) (*sua*

*sponte* convening *en banc* regarding issues of willful infringement and the possible need to overrule conflicting cases). But the court evidently did not feel that *en banc* review was desirable. Instead, *Allergan* issued as a unanimous *per curiam* panel opinion applying and affirming the holding in *Warner-Lambert*. *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322 (Fed. Cir. 2003), *rehearing en banc denied* (May 22, 2003).

The Federal Circuit's decision to deny Allergan's petition for rehearing *en banc* was likewise unanimous. *See Allergan, Inc. v. Alcon Labs., Inc.*, Fed. Cir. Docket No. 02-1449 (Order of May 22, 2003). Thus, not even a single judge on the *Allergan* panel went on record to oppose denial of rehearing *en banc*.

Despite the abstract intellectual disagreement between the *Warner-Lambert* panel and the *Allergan* concurrers, the Federal Circuit found the case undeserving of *en banc* review. The law in the Federal Circuit—and across the country—is thus uniform: no cause of action exists under § 271(e)(2)(A) for infringement of method-of-use patents that claim off-label uses. This Court's intervention is not warranted.

## II. The Federal Circuit's *per curiam* opinion is consistent with both the plain language and the purpose of the Hatch-Waxman Act.

At issue here is the proper construction and interpretation of § 271(e)(2)(A), which provides in pertinent part:

> It shall be an act of infringement to submit [an ANDA] for a drug . . . the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under [the Hatch-Waxman Act] to engage in the commercial manufacture, use, or sale of

> a drug . . . the use of which is claimed in a patent before expiration of such patent.

35 U.S.C. § 271(e)(2)(A). In *Warner-Lambert*, the Federal Circuit addressed whether Congress intended to limit actions for infringement of method-of-use patents under § 271(e)(2)(A) to patents that claim an FDA-approved use of a drug. *See Warner-Lambert*, 316 F.3d at 1354. In a thorough, well-reasoned decision, the panel answered that question yes, holding "it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent and the patent at issue is for a use not approved under the NDA." *Id.* at 1354-55.

This analysis was and is correct, as the entire Federal Circuit later implicitly acknowledged when it denied *en banc* rehearing in the case at bar. The plain language of § 271(e)(2)(A)—the initial focus in a statutory construction analysis, *see Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438, 119 S. Ct. 755, 760 (1999)—indicates that it applies only to an ANDA that seeks approval for the patented use. But because an ANDA may never seek approval for an *off-label* use of a drug, *see* 21 U.S.C. § 355(j)(2)(A)(i), it follows that this provision does not apply to an off-label use patent. In other words, the term "the use" in § 271(e)(2)(A) refers to "the" FDA-approved use, "the" only use for which an ANDA applicant can ever seek approval. That Congress chose to use the definite and particularized article "the" in referring to "the drug" is also significant because "the" is a word of limitation that refers to a specific use, which in this case must be the FDA-approved use listed in the NDA. *See Am. Bus. Ass'n v. Slater*, 231 F.3d 1, 4-5 (D.C. Cir. 2000).

This construction of § 271(e)(2)(A) is reinforced by reading the Hatch-Waxman Act as a whole, and in conjunction with its underlying purpose, as it must be read. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669, 110 S. Ct. 2683, 2688 (1990) (affirming interpre-

tation of § 271(e)(1) that best fit with the structure of the Hatch-Waxman Act taken as a whole); *U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455, 113 S. Ct. 2173, 2182 (1993) ("[I]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.") (internal quotations and citation omitted); *Kokoszka v. Belford*, 417 U.S. 642, 650, 94 S. Ct. 2431, 2436 (1974) (court must give statute "such a construction as will carry into execution the will of the Legislature.") (internal quotations and citation omitted). The *Warner-Lambert* construction is consistent with the legislative purpose of Hatch-Waxman, which is "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

On the other hand, the construction advanced by Allergan would thwart that salutary purpose by permitting an NDA-holder to forestall generic competition indefinitely—even where the applicant seeks approval to market an off-patent drug for an off-patent use. Congress did not intend such a result, and Allergan does not explain how its construction—which is very good for NDA-holders but would squelch generic competition altogether—can be squared with the underlying purpose of Hatch-Waxman.

The *Warner-Lambert* panel's construction of § 271(e)(2)(A) is also the only interpretation consistent with Hatch-Waxman's patent-listing and patent-certification provisions. Only information on method-of-use patents that claim a method of using the drug for which the NDA was submitted may be submitted to the FDA for listing in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA has interpreted this provision to mean that only patents that claim an approved use of the NDA drug should be submitted for listing in the Orange Book. *See* 21 C.F.R. § 314.53(b)(1). Likewise, an ANDA applicant need certify only to a use patent that

"claims a use for such listed drug for which the applicant is seeking approval," 21 U.S.C. § 355(j)(2)(A)(vii), which necessarily excludes off-label method-of-use patents since an ANDA applicant may never seek approval for an unapproved use of a drug. The legislative history is in accord. *See* H.R. Rep. No. 98-857, pt. 1, at 22 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2655 (applicant must submit certification only for use patents that claim an indication for which the applicant is seeking approval).

This is also the only interpretation of § 271(e)(2)(A) that does not lead to absurd results and run afoul of the patent laws. *See Clinton v. City of New York*, 524 U.S. 417, 429, 118 S. Ct. 2091, 2098 (1998) (statutes should be interpreted to avoid absurd results). NDA-holders have argued that, under § 271(e)(4), a finding of infringement entitles the patentee to an order barring approval of the ANDA altogether for the life of the asserted patent. *See* 35 U.S.C. § 271(e)(4). By allowing an off-label use patent to be asserted under § 271(e)(2)(A), as Allergan seeks to do here, a patentee could prevent marketing of the drug for any use, even admittedly non-infringing or off-patent uses—an absurd result that is, in the words of the *Allergan* district court, "akin to using a sledgehammer to squash an ant." *Allergan, Inc. v. Alcon Labs., Inc.*, 200 F. Supp. 2d 1219, 1232 (C.D. Cal. 2002). Such an interpretation also runs afoul of the patent laws, under which off-patent subject matter passes to the free use of the public. A patentee has the right to exclude others from practicing only that which infringes. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152, 109 S. Ct. 971, 978 (1989).

Thus, all the relevant tools of statutory construction point to the same conclusion and mandate that § 271(e)(2)(A) be interpreted consistent with the *per curiam* opinion below and *Warner-Lambert*—to exclude off-label method-of-use patents.

## III. The statutory interpretation established in *Warner-Lambert*, and upheld in *Allergan*, is in the public's best interest, is consistent with this Court's precedent, and provides no disincentives to research new uses for existing drugs.

Contrary to Allergan's contentions, the Federal Circuit has not created a disincentive for researching new uses of old drugs. The incentive for NDA-holders created by Hatch-Waxman was patent-term restoration, which applies only where the NDA-holder makes the investment to obtain FDA approval for a patented drug product or use in order to benefit the consuming public. *See Eli Lilly*, 496 U.S. at 670-71, 110 S. Ct. at 2689. Nothing suggests that Congress intended to confer any benefit on an NDA-holder, like Allergan here, that strategically decided *not* to make that investment. *Warner-Lambert*, 316 F.3d at 1359 ("There is no evidence that Congress intended to enable an innovator to extend its exclusivity merely by asserting patents on unapproved uses.").

Although Allergan extols the fact that it has invested money into researching brimonidine's neuroprotective uses, Allergan admits it did not perform the studies required for FDA approval of these uses. Allergan tried to obtain patent protection on the use of brimonidine to reduce intraocular pressure and as a neuroprotectant, but the Patent Office rejected a patent for the former use and Allergan settled for patent protection only on neuroprotection. Allergan did not appeal these rejections to the Board of Patent Appeals or the courts. As such, Allergan settled for patent protection on a use for which it chose *not* to pursue FDA approval. Nothing legally precluded Allergan from pursuing FDA approval on the patented neuroprotection. Had it done so, it could have had patent protection on a use for which it has FDA approval, and it could have used that protection against later generic ANDA-filers. But Allergan did not do so. Thus, Allergan

is where it is due to its own decisions, and not any error by the Federal Circuit.

Nevertheless, Allergan still has the ability to sue a generic-drug manufacturer for inducement of infringement once the generic company brings its product to market. Under the construction applied in the *per curiam* opinion below, Allergan simply does not get the rewards that Hatch-Waxman bestows on those who undertake the effort to seek FDA approval on a patented use. Otherwise, Allergan's patent rights are unaffected, and are the same now as they were before *Warner-Lambert*, *i.e.*, they can be used to prevent the active and knowing promotion and inducement of the protected off-label use once the generic proceeds to market. The only difference is that Allergan does not get the free 30-month injunction without actually proving a likelihood of success on the merits of its infringement claim, together with the other elements necessary for such injunctive relief.

While Allergan complains that a post-marketing preliminary injunction against a generic manufacturer is "illusory," Allergan's real complaint is that such an injunction might be hard to get or would not be broad enough to inhibit all market access to a product that has substantial non-infringing or unpatented uses. But under the patent laws, one is not entitled to enjoin non-infringing or unpatented uses, a fundamental proposition not at issue here. *See Bonito Boats*, 489 U.S. at 152, 109 S. Ct. at 978 ("We have long held that after the expiration of a federal patent, the subject matter of the patent passes to the free use of the public as a matter of federal law."). Allergan thus simply wants more than it is entitled to under the patent laws.

The statutory construction proposed by Allergan actually creates a perverse incentive, encouraging NDA-holders to refrain from seeking FDA approval for patented uses:

> [H]olders of method-of-use patents can benefit by *not* seeking FDA approval for the patented use. By so doing, they force the generic manufacturers to file paragraph IV certifications, which then triggers the thirty-month extension that Hatch-Waxman adds to their period of exclusivity.

*Organon Inc. v. Teva Pharms., Inc.*, 244 F. Supp. 2d 370, 374 n.5 (D.N.J. 2002).

In sum, Allergan did nothing more than list patents that block generic competition with no corresponding value to patients. There is no need for an incentive to encourage *that* type of conduct.

Finally, Allergan's contention that the Federal Circuit's interpretation of § 271(e)(2) threatens future disruptions in healthcare is unfounded. Allergan's argument teeters on the uncertain premise of an injunction against a generic manufacturer, followed by the unlikely possibility that a doctor will be unable to find another prescription drug product to take the place of the generic drug and prevent withdrawal symptoms. Allergan cannot demonstrate how often, if ever, this unlikely chain of events might occur, nor can it show why the mere threat of possible disruptions means that patients would be better off *not* having faster access to lower-cost drug products.

Companies like Allergan have the same financial incentives to develop new drugs now as they did before *Warner-Lambert*, and the public interest is served by the elimination of the 30-month stay that can accompany a suit brought by an NDA-holder on an off-label use patent.

## CONCLUSION

For these reasons, the petition should be *denied*.

Respectfully submitted,

Christine J. Siwik
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
(312) 558-5600

William A. Rakoczy
Hugh S. Balsam
Shashank S. Upadhye*
Lara E. Monroe-Sampson
LORD, BISSELL & BROOK LLP
115 South LaSalle Street
Chicago, IL 60603
(312) 443-0700

*Counsel for Amicus Curiae*
*Generic Pharmaceutical Association*

October 24, 2003

*Counsel of Record